IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOYCE BONCHER, Plaintiff,	:	
v.	:	Civil No. 5:24-cv-01403-JMG
3M COMPANY, *et al.*, Defendants.	:	

MEMORANDUM OPINION

GALLAGHER, J. **February 14, 2025**

I. OVERVIEW

Plaintiff alleges that the Bair Hugger Warming Blanket device ("Bair Hugger") used in the operating room ("OR") during her knee revision surgery caused her to develop a periprosthetic joint infection ("PJI"). She has alleged claims of negligence, failure to warn, design defect, breach of implied warranty of merchantability, fraud, and unjust enrichment. Defendants have moved to exclude the testimony of all of Plaintiff's proffered general and specific causation experts under Federal Rule of Evidence 702. Defendants have also moved for summary judgment. The Court finds Plaintiff's general and specific causation experts' opinions are admissible. There are also genuine disputes of material fact regarding the applicability of the discovery rule to toll the statute of limitations, and elements of her claims of negligence, failure to warn, design defect, and fraud. Defendants' motion to exclude and motion for summary judgment is denied.

II. BACKGROUND

This case was transferred to this Court from the District of Minnesota to serve as a bellwether trial for the larger MDL proceeding *In Re: Bair Hugger Forced Air Warming*

Products Liability Litigation, MDL No. 15-2666-JNE. Plaintiff alleges that the Bair Hugger designed, manufactured, and distributed by Defendants caused contaminants to be introduced into her surgical wound site resulting in the development of a PJI. First Amend. Compl. ("ECF No. 63"), at ¶¶ 8, 14.

Plaintiff underwent knee revision surgery on August 22, 2018, after she was injured from a fall into her daughter's swimming pool." Pl.'s Resp. to Defs' Statement of Disp. Facts ("RSUMF"), ECF No. 85-1, at P ¶ at 2. [1] Orthopedic surgeon Dr. Brett Godbout performed the surgery at the Coordinated Health in Bethlehem, Pennsylvania. ECF No. 63, at ¶ 9. The Bair Hugger forced air warming device was used during Plaintiff's surgical procedure to prevent her core body temperature from dropping, thus mitigating the risk of hypothermia. *See* RSUMF, at R ¶ 9. *Id*. at ¶¶ 9, 12. The Bair Hugger works by warming air in an internal heating unit, transporting it through a hose, and distributing it over the patient's chest and arms through a perforated blanket placed on top of them during surgery. *See id*. at R ¶ 5.

On October 19, 2018, a little under two months after her knee revision surgery, Plaintiff was diagnosed with a "serious" PJI. Defendants' Statement of Undisputed Material Facts ("SUMF"), ECF No. 86-1, at ¶ 25. Treatment of the PJI involved twice-daily infusions of antibiotics and four additional surgeries, "including removal of the implant from her infected knee in February 2019 and another total knee revision in June 2019." RSUMF, at P ¶¶ at 5-6. At the time, Plaintiff's treating physicians were unable to determine what caused her infection.[2] *Id*.

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[1] Plaintiff has both responded to Defendants' Statement of Undisputed Material Facts and provided her own Counterstatement of Facts in ECF No. 85-1. To avoid confusion, the Court will reference paragraphs in this document as either "R ¶" for responses to Defendants' statement or "P ¶" for Plaintiff's counterstatements.

[2] Dr. Godbout did not learn that the Bair Hugger could increase airborne contamination in the OR until after this lawsuit was filed, but he now opines that her infection was "'very likely caused' by air contamination from the Bair Hugger forced air warming device," as will be

at P ¶¶ at 10, 12. Plaintiff and Defendants agree that "the source of [her] decision to file a lawsuit relating to the Bair Hugger stemmed from [a] call out of the blue that [she] received from some unidentified person asking about infection and wanting [her] to sign an authorization." SUMF, at ¶ 31. However, the parties dispute when this call occurred, with Defendants claiming that it was sometime in March of 2021, and Plaintiff asserting that it occurred on September 7, 2021, the same day she retained her current lawyers. SUMF, at ¶ 26; Plaintiff's Opp. to Mot. for Summ. J. ("ECF No. 85"), at 12-13. Plaintiff was not familiar with the Bair Hugger device or its use in her surgical procedure until September 9, 2021. RSUMF, at P ¶¶ 19, 23.

Plaintiff filed suit in the Bair Hugger MDL on August 4, 2023. SUMF, at ¶ 32. Plaintiff's Amended Complaint brings claims of negligence, failure to warn, design defect, breach of implied warranty of merchantability, fraud, and unjust enrichment. ECF No. 63.[3] Before the Court are Defendants' omnibus motion to exclude testimony from Plaintiff's general and specific causation experts ("ECF No. 70") and Defendants' motion for summary judgment ("ECF No. 71").

III. MOTION TO EXCLUDE

Defendants have moved to exclude certain testimony and opinions of Plaintiff's five general causation medical experts, one general causation engineering expert, and three specific causation experts under Federal Rule of Evidence 702. The opinions of the general causation experts are offered to establish that the Bair Hugger is capable of causing PJIs in surgical patients, and the specific causation experts' opinions are offered to establish that the Bair Hugger

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discussed in more depth later in this opinion. RSUMF, at P ¶¶ 10-11 (internal quotations omitted).

[3] Plaintiff has informed the Court in her opposition brief that she does not intend to pursue her claims of unjust enrichment and breach of implied warranty at trial. ECF No. 85, at 2 n.1. The Court finds that Plaintiff has waived these causes of action. *See McCowan v. City of Phila.*, 603 F.Supp.3d 171, 193 (E.D. Pa. 2022).

did in fact cause Plaintiff's PJI. *See Ream v. Ethicon, Inc.*, 2020 WL 6889238, at *4 (M.D. Pa Nov. 24, 2020). In anticipation of this motion, counsel for the Plaintiff raised objections with the Court during a telephonic status conference held on December 3, 2024. Plaintiff's counsel argued that it was improper for Defendants to raise again challenges to the opinions of Plaintiff's general causation medical experts whom the Eighth Circuit Court of Appeals found to be reliable in the MDL proceeding.[4] *See In Re: Bair Hugger Forced Air Warming Products Liability Litigation ("Amador"),* 9 F.4th 768, 788-890 (8th Cir. 2021). This prompted the Court to order supplemental briefing on the matter of whether Defendants should be permitted to challenge the ruling of the Eighth Circuit on general-causation medical experts in a *Daubert* Motion before this Court. ECF No. 60. In addition to the requested supplemental briefing, the Court has considered the parties' related briefing in support of and in opposition to Defendants' omnibus motion to exclude.

As a threshold matter, the parties dispute the applicability of the law of the case doctrine to this bellwether trial in a separate circuit from the MDL proceeding. The first question to decide is whether it is proper for this Court to resolve Defendants' motion to exclude Plaintiff's general causation medical experts, or whether the Eighth Circuit's decision in *Amador* to admit those experts' opinions is binding on this Court under the law of the case doctrine. The Court

[4] Defendants raised a similar challenge to the MDL Court for reconsideration of "the Eight Circuit's general causation determinations on grounds that [recent amendments to Federal Rule of Evidence 702] changed the legal standard for admissibility of expert testimony and that new science since the Eighth Circuit's decision 'justified revising general causation.'" P's Supp. Brief on General Causation ("ECF No. 76"), at 3. This request for reconsideration was denied. *Id*. at 4.

agrees with Defendants that the law of the case doctrine is not applicable here, and it is permitted to review Defendants' motion to exclude.[5]

Generally, "[t]he law of the case doctrine prevents reconsideration of legal issues already decided in earlier stages of a case[,]. . . only applies within the same case, . . . and affects only issues that were expressly or necessarily resolved by prior decisions in the same case." *Home Depot USA, Inc. v. Lafarge North America, Inc.*, 59 F.4th 55, 61 (3d Cir. 2023) (internal citations and quotations omitted). In *Home Depot USA*, the Third Circuit concluded that the plaintiff was not bound by rulings issued in the MDL before it joined it. *Id*. at 61-62. The Third Circuit opined that "different cases brought together in an MDL remain separate," therefore, "[t]he law of the case doctrine cannot be applied across distinct actions in this multidistrict proceeding. . . . That means a district court's decision whether to grant a motion . . . in an individual case depends on the record in that case and not others." *Id*. at 61 (internal citations and quotations omitted); *In re National Football League Players' Concussion Injury Litigation*, 2024 WL 2012241, at *12 (E.D. Pa. April 29, 2024); *see In re Google Digital Advertising Antitrust Litigation*, 2025 WL 289726, at *8 (S.D.N.Y. Jan. 24, 2025) ("In an MDL proceeding, where multiple cases are consolidated for pretrial supervision, each action is formally a separate case and the law of the case doctrine does not apply in [a] separate action." (internal quotations omitted)).

Under this rationale, the Court finds that Plaintiff's case is not the "same case" as *Amador*. Plaintiff's complaint was filed separately two years after the Eighth Circuit's decision to reverse summary judgment and admit the general causation medical experts. Plaintiff's case was then remanded from the MDL to this Court "for case-specific discovery, dispositive motions

[5] Because the Court has found that the doctrine of law of the case does not apply all together, it does not need to address the parties' disputes over the applicability of the various exceptions to the doctrine.

practice, and trial" and she plans to admit two new medical experts that were not proffered in *Amador*. ECF No. 76, at 4. The case also involves different parties, as Plaintiff was not involved in the MDL at the time *Amador* was decided.[6]

Lastly, the Court notes that applying the law of the case doctrine here from a decision in the Eighth Circuit to a bellwether trial in the Third Circuit would be inconsistent with the principle that a district court has "no obligation to follow a decision from another circuit." *In re Pennsylvania Title Ins. Antitrust Litig.*, 648 F. Supp. 2d 663, 675 (E.D. Pa. 2009); *see Rogers v. Grewal*, 2018 WL 2298359, at *3 (D.N.J. May 21, 2018) (quoting *Villines v. Harris*, 487 F. Supp. 1278, 1279 n.1 (D.N.J. 1980) ("Decisions of the Court of Appeal for a given circuit are binding on the district courts within the circuit, but are not binding on courts in other circuits."). This proposition provides further support for the Court's ruling that it is not precluded from resolving the motion to exclude.

Nonetheless, even though this Court is not bound by the Eighth Circuit's findings in *Amador*, the Court is persuaded by its analysis and reaches the same conclusions as to Plaintiff's general causation experts.

A. Federal Rule of Evidence 702

"Under the Federal Rules of Evidence, a trial judge acts as a gatekeeper to ensure that any and all expert testimony or evidence is not only relevant, but also reliable." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (internal quotations omitted). "Rule 702 has a liberal policy of admissibility," so long as an expert meets the requirements of qualification,

[6] To the extent Plaintiff argues that allowing Defendants to move to exclude her general causation medical experts would upend the findings of the MDL Court in *Amador*, this Court disagrees. The cases are distinct from one another, and this Court's decision to hear Defendants' *Daubert* motion does not reverse the MDL Court's decision to reject Defendants' request to file a renewed *Daubert* motion in that case.

reliability, and fit. *Nat'l Fire & Marine Ins. Co. v. Newtown Square, LLC*, 2024 WL 1683609, at *2 (E.D. Pa. Apr. 18, 2024) (citing *Kannankeril v. Terminix Int'l, Inc.,* 128 F.3d 802, 806 (3d Cir. 1997), *as amended* (Dec. 12, 1997)). *J.L. v. Lower Merion Sch. Dist.*, 2024 WL 5227410, at *3 (E.D. Pa. Dec. 26, 2024). Rule 702 was amended in 2023, and currently reads:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

FED R. EVID. 702. Despite Defendants' contentions, the text of Rule 702 has not been substantively altered other than to clarify that "the party proposing the expert witness must show that each prong [of admissibility]—qualification, reliability, and fit—is satisfied by a preponderance of proof." J.L. v. Lower Merion Sch. Dist., 2024 WL 5227410, at *4; *Johnson v. Comodo Group, Inc.*, 2024 WL 2933195, at *4 n.6 (D.N.J. June 10, 2024); *Power v. Hewlett-Packard Co.*, 2024 WL 4040432, at *3 (W.D. Pa. July 19, 2024). However, many courts, including the Eighth Circuit, had already been applying this standard prior to the amendment. *See Amador*, 9 F.4th at 776 ("As the proponent of the expert testimony in question. Plaintiffs have the burden to prove its admissibility by a preponderance of the evidence."). The recent amendment to Rule 702 also "emphasizes a court must evaluate the reliability of an expert's conclusions drawn from his or her methodology, not just the methodology itself." *Power v. Hewlett-Packard Co.*, 2024 WL 4040432, at *4 (W.D. Pa. July 19, 2024).

The first requirement of expert testimony admissibility is qualification. "Qualification requires that the witness possess specialized expertise, and the Third Circuit has explained that a broad range of knowledge, skills and training qualify an expert." *Phila. Trust Co. v. Temple Univ. Hosp., Inc*., 2024 WL 5057595, at *2 (E.D. Pa. Dec. 9, 2024) (internal quotations omitted*); see Pineda,* 520 F.3d at 244. This is admittedly a low bar, even with the recent amendment to Rule 702. *See Philadelphia Trust Co.*, 2024 WL 5057595, at *2. The specialized expertise or knowledge required can come from "practical experience as well as academic training and credentials." *Id*. (internal quotations omitted).[7]

Second, "Rule 702's reliability threshold requires expert testimony to be based on the methods and procedures of science, not on subjective belief and unsupported speculation." *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 833-34 (3d Cir. 2020) (internal quotations omitted). In other words, the expert must utilize a reliable technique or process to form the basis of their opinion, which is what courts refer to as "good grounds." *Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 80-81 (3d Cir. 2017); Pineda, 520 F.3d at 247. "'Ultimately, the purpose of the reliability requirement is to make certain an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the field.'" *J.L. v. Lower Merion Sch. Dist.,* 2024 WL 5227410, at *7 (quoting *Keller v. Feasterville Family Health Care Ctr.*, 557 F. Supp. 2d 671, 676 (E.D. Pa. 2008)). "While there is no definitive checklist or test" for determining whether an expert's testimony is based on good grounds, courts are encouraged to evaluate:

[7] Defendants do not challenge the qualification of Plaintiff's causation experts; therefore, the Court will not analyze this requirement. ECF No. 70, at 9.

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

Cohen v. Cohen, 2025 WL 45704, at *4 (3d Cir. Jan. 8, 2025) (internal quotations omitted). However, although the expert must use "good grounds" to reach their conclusion, they do not need to be the "best grounds." *J.L. v. Lower Merion Sch. Dist.*, 2024 WL 5227410, at *4. The advisory committee's note to the 2023 amendment adds that "if the court finds it more likely than not that an expert has a sufficient basis to support an opinion, the fact that the expert has not read every single study that exists will raise a question of weight and not admissibility." FED R. EVID. 702 advisory committee's note to 2023 amendment.

Third, Rule 702 provides that an experts testimony "fits" the proceedings if it "will [more likely than not] help the trier of fact to understand the evidence or to determine a fact in issue." FED R. EVID. 702(a). "This condition goes primarily to relevance, . . . so an expert's testimony will be excluded if it is not scientific knowledge *for purposes of the case*." *Cohen*, 2025 WL 45704, at *5 (internal citations and quotations omitted).

B. General Causation Experts

1. Dr. Said Elghobashi

Defendants challenge the admissibility of testimony by Dr. Said Elghobashi, a "preeminent authority in the field of computational-fluid-dynamics ("CFD"). Pl.'s Opp. to Mot. to Exclude ("ECF No. 84"), at 3. Dr. Elghobashi developed a CFD simulation which used a three-dimensional design to replicate an orthopedic OR and analyze how forced-air warming devices impact the performance of ultra-clean ventilation systems. Elghobashi Rep., ECF No. 70-11, at 6-7. Based on the results of his simulation, he concluded that the Bair Hugger is

capable of "mobiliz[ing] numerous squames [human skin cells large enough to carry bacteria] on the OR floor and transport[ing] them to the surgical site and table where the prosthesis and tools are located." ECF No. 84, at 4; ECF No. 70-11, at 62. His report also advised that the presence of additional OR conditions such as the movements of surgeons and medical assistants would further increase the "probability of dispersing the squames to the surgical site." ECF No. 70-11, at 62. Defendants seek to preclude Dr. Elghobashi's opinion on the basis that his testimony does not "fit" the facts of the case and is unreliable. ECF No. 70, at 9.

Defendants claim that Dr. Elghobashi's opinion is unreliable, and he lacks the foundation to conclude that the Bair Hugger can cause PJIs in a "real-world" OR where he has only tested it in a hypothetical OR. *Id*., at 11. In support of this, Defendants point to multiple variables in Plaintiff's OR that his hypothetical model failed to account for, including the arrangement and number of airflow diffusers, temperature, number of medical staff present and their movements, air change rate, and size of the room. *Id*. at 10-11. This argument was addressed by the Eighth Circuit which agreed that neither Dr. Elghobashi's published study, nor his expert report provided good grounds for his conclusion that additional variables in the OR would increase the dispersion of particles in the OR from the Bair Hugger. *Amador,* 9 F.4th at 782.

However, in finding that Dr. Elghobashi's testimony was still relevant and admissible "insofar as [it] provided part of the factual basis for Plaintiffs' medical experts' general-causation opinions," the Eighth Circuit admitted it on a limited basis. *See id*. at 783 n.6. Although Dr. Elghobashi's opinion about the effect that untested OR variables might have on the Bair Hugger's dispersion of squames lacked a sufficient basis, he had good grounds for concluding that the Bair Hugger was capable of dispersing squames into the surgical site, at least under the conditions present in his model. *Id*. at 782-83 ("Dr. Elghobashi set out to determine

whether forced-air warming 'play[s] a role in transporting squame particles to the surgical site'; his CFD model tested this hypothesis; and he found that forced-air warming does play a role, at least in certain OR conditions with limited airflow disruptions from other sources.").

We agree with the Eighth Circuit's ruling on the limited admissibility of Dr. Elghobashi's testimony, and find no further analysis is necessary, as both reliability and fit have been proven by a preponderance of the evidence.[8]

2. Drs. William Jarvis, Jonathan Samet, Michael Stonnington, Jack Bowling, and Bernard Camins

Defendants next challenge the admissibility of testimony by medical experts on two general causation theories for how the Bair Hugger can cause PJIs. Defendants challenge all five medical experts offered to testify about these theories: [9]

- Dr. Jarvis: a medical doctor "with extensive experience in the areas of infectious disease, healthcare epidemiology, infection control, and pediatrics." Jarvis Rep., ECF No. 70-13, at 1.
- Dr. Samet: a board-certified internist and pulmonary physician and fellowship-trained epidemiologist whose "research has addressed exposure to airborne particulate

[8] Defendants raise an additional argument in a footnote that a "more reliable" CFD model has disproven Dr. Elghobashi's opinions. ECF No. 70, at 11 n.4. In the absence of any showing from Defendants as to how this impacts the admissibility of Dr. Elghobashi's testimony, the Court finds that this argument would be better addressed at trial through cross-examination or the presentation of a competing expert. *See Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 83 (3d Cir. 2017) (explaining that challenges to a study's results ordinarily goes to the weight of the evidence not the admissibility).

[9] Both Plaintiff and Defendants agree that "[a]ll of these experts' general causation opinions rely on largely the same materials [previously considered by the Eighth Circuit] in concluding that the Bair Hugger is capable of causing PJIs based on the air-flow disruption theory and dirty-machine theory." *Id*. at 4-5; ECF No. 70-1, at 4 n.3. Therefore, their opinions will be consolidated for purposes of the Rule 702 analysis.

matter" and who has "provided care for numerous patients with infectious diseases, some complicating surgery." Samet Rep., ECF No. 70-12, at 1-3.

- Dr. Stonnington: a board-certified orthopedic surgeon "with a special interest in Total Joint Replacement and Traumatology," Stonnington Rep., ECF No. 70-14, at 2,
- Dr. Camins: a professor of medicine "trained in internal medicine and infectious diseases." Camins Rep., ECF No. 70-27, at 1.
- Dr. Bowling: "a board-certified orthopaedic surgeon with extensive experience in the diagnosis, management (both operative and nonoperative) of disorders of the hip and knee with special emphasis on adult reconstructive or joint replacement surgery." Bowling Rep., ECF No. 70-3, at 1.

These general causation medical experts propose two plausible mechanisms by which the Bair Hugger could introduce bacteria into a surgical site to cause infection. Under the dirty-machine theory, the Bair Hugger is the source of the infection-causing bacteria, and its "internal contamination is capable of escaping the blanket and reach[ing] the surgical site." ECF No. 84, at 7 (internal quotations omitted). Under the airflow-disruption theory, "waste heat from [the] Bair Hugger [disrupts the OR airflow and] increases airborne contamination near the incision site." *Id*. at 9; ECF No. 70-27, at 5. Defendants argue that the medical experts' general causation theories are unreliable because they "lack good grounds and depend on analytical gaps that are too great under Rule 702." ECF No. 70-1, at 12. However, this Court again disagrees.

Defendants' brief devotes significant attention to the McGovern 2011 observational epidemiological study that identified an increased risk of surgical site infections from the use of forced-air warming devices which disrupted the clean airflow patterns over the surgical site. *See* McGovern 2011, Ex. O, ECF No. 70-17, at 1541. McGovern 2011 reviewed infection data from

hip and knee replacement patients warmed convectively versus conductively. *See id*. at 1541. McGovern 2011 reported an association between the use of the Bair Hugger in ORs and surgical site infections, but "did not establish a causal basis" for this increased risk. *Id*. at 1543. Relying on additional peer-reviewed studies to support their general causation opinions, the medical experts proposed the dirty-machine and airflow-disruption theories as plausible causation explanations for this association. *See* ECF No. 86, at 2. The Court notes Defendants' objections to the limitations of the design and implementation of the McGovern 2011, including its failure to avoid or address potential confounding by other infection control measures instituted by the hospital. *See id*. at 1543. However, these limitations and potential shortcomings in the research do not make the study *per se* unreliable, as the strength of the study goes to its weight, not admissibility. Additionally, the experts' opinions which draw inferences of causation from the associations identified in the study are not unreliable because the other studies provide a sufficient scientific basis for these opinions. *See Amador*, 9 F.4th at 779-780 (quoting Federal Judicial Center, *Reference Manual on Scientific Evidence* at 218 (3d ed. 2011)) ("So long as an expert does the work "'to bridge the gap between association and causation,' a study disclaiming having proven causation may nevertheless support such a conclusion."). The Court might have reached a different conclusion as to the reliability of experts' general causation opinions had they been based solely on this study, that is not the case here, as will be discussed below.

The Eighth Circuit found that the dirty-machine theory was plausible where sufficient evidence was provided to support the following four premises:

> First, the Bair Hugger internally must harbor bacteria in either the central unit or the hose. Second, the Bair Hugger must be capable of blowing that internal contamination into the blanket. Third, that internal contamination must be capable of escaping the blanket. And fourth, that internal contamination must be able to reach the surgical site.

Amador, 9 F.4th at 786. Defendants concede that the experts cite "some evidence that bacteria has been found inside the Bair Hugger systems," and the operation of the Bair Hugger system involves the movement of warmed air forced through an outlet house into the blanket, meaning the Bair Hugger is capable of blowing internal contamination into the blanket, but they dispute the third and fourth premises. ECF No. 70-1, at 12-13. They contest that this theory cannot be admissible because Plaintiff's "[m]edical [e]xperts have no evidence that those particles could [escape the blanket to] reach the surgical site and cause infection." *Id*. at 13.

The Court finds there is sufficient factual support for the third and fourth premises, and the medical experts' opinions on the dirty-machine theory are predicated on good grounds. For instance, the experts cite to a 2017 report which concluded that particles could escape the Bair Hugger blanket from the inside after observing an incident where the Bair Hugger "deposited soot on a patient's body in the pattern of the holes in the Bair Hugger blanket." *See* Camins Rep., ECF No. 70-27, at 7. They also reference a 2021 study which, after observing higher bacterial counts in the Bair Hugger outlet hoses that push air through the porous blankets than in the surrounding OR air following a surgical procedure, concluded that "the [Bair Hugger] is likely a direct contributor to an increased burden of airborne microbes [resulting in contamination] in the OR." Brock-Utne 2021, Ex. J, ECF No. 82-11, at 59, 63. There is also deposition testimony from representatives of Defendants which confirms that the Bair Hugger is capable of increasing the particle count over the sterile field, which supports the fourth premise. ECF No. 70-27, at 9. In further support of the fourth premise, "some of the airflow-disruption studies the experts relied on reported that air from where the blanket exhausted waste heat reached the surgical site and that certain draping arrangements would facilitate that." *Amador*, 9 F.4th at 787; s*ee*, *e.g.,* Belani 2013, ECF No. 70-18, at 5. Although the Court has only discussed some of the sources experts

considered in reaching their opinions about the plausibility of the dirty-machine theory, these sources provide empirical support for the four premises underlying this theory and persuade the Court that these experts used good grounds to reach their conclusions. Although Plaintiff's medical experts did not personally test the air expelled from the Bair Hugger for contamination, this is not dispositive to the reliability of their opinions where other scientific data demonstrates the presence of this contamination inside the hose and around the surgical site. The Court finds the purported analytical gap between the data gleaned from these studies and the general causation opinion of the medical experts is not so great as to make the opinion unreliable for our purposes.

As to the airflow disruption theory, Defendants argue that the medical experts rely on studies and the Elghobashi CFD model, none of which reflects "real-world" conditions which would allow them to draw conclusions about the effect of the Bair Hugger in an OR with other sources of movement present. ECF No. 70-1, at 15. As discussed above, Dr. Elghobashi's testimony is reliable and admissible for the proposition that the Bair Hugger is capable of transporting squames to the surgical site under certain OR conditions. However, the Court must now address whether there is sufficient support under the airflow-disruption theory for these experts to conclude that the Bair Hugger would still increase particle-laden airflow over the surgical site in a real-world OR. *See Amador*, 9 F.4th at 784-85.

Again, we concur with the Eighth Circuit's finding that these experts rely on studies which "provide empirical support bridging the analytical gap from simulated [OR] conditions to real-world [OR] conditions." *Id.* at 785. Of relevance are the McGovern 2011 study and the Belani 2013 study:

> [I]n McGovern 2011, the authors noted how the surgical lighting, drapes, and personnel in their study created "fragile [airflow] conditions" that facilitated the Bair Hugger's

> ability to disrupt airflow significantly enough to transmit air from nonsterile areas of the [OR] to the surgical site. . . Similarly, in Belani 2013, the authors found that surgical lighting and drapes magnified the Bair Hugger's effects. . .

Id. (internal citations omitted). Plaintiff's medical experts also rely on more recent studies which tested forced air warming devices actively used in OR settings under "real-world" conditions. ECF No. 84, at 11. One study which tested Colony Forming Unit pathogen levels in the air and on the surfaces of forced air warming devices "identified a correlation of positive airborne samples for instances that had high-pathogen contamination in the warmed-temperature components [of the forced air warming devices], resulting in . . . possible attributable [surgical site infections]." Lange 2019, Ex. E, ECF No. 82-6, at 2. Another study observed that surgical site infection "rates were higher in patients who underwent warming with forced air devices than with devices using conduction." Kim 2023, Ex. T, ECF No. 82-20, at 1328. The Court finds these studies are sufficient to justify the medical experts in concluding that the Bair Hugger would still increase airborne contamination over the surgical site in the presence of real-world OR conditions in support of the airflow-disruption theory.

"[I]n order to exclude expert testimony, the 'gap' [between the data and opinion proffered] must be extreme." *Nichols v. Morrisey*, 2024 WL 871322, at *5 (E.D. Pa. Feb. 29, 2024). The Court finds that the medical experts' plausible mechanisms explaining the association between the use of the Bair Hugger in an OR and increased particle counts over the surgical site are based on reliable methodology which draws causal inferences from associations identified in peer-reviewed scientific literature and case studies. Although the Court is to serve as a gatekeeper in ensuring that expert opinions meet the requirements of qualification, reliability, and fit, "a gatekeeper alone does not protect the castle," and Defendants are reminded that "[a] party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts, and assumptions as the basis for is opinion can highlight those weaknesses

through effective cross-examination." *U.S. v. Mitchell*, 365 F.3d 215, 245 (3d Cir. 2004) (internal quotations omitted). Defendants' concerns regarding the strength of the studies Plaintiff's medical experts relied on or the conclusions the experts have drawn from them can be challenged on cross-examination. Plaintiff's medical experts' general causation opinions are reliable.

C. Specific Causation Experts

Defendants also seek the exclusion of Plaintiff's specific causation medical experts, Drs. Jack Bowling, Bernard Camins, and Brett Godbout, for "fail[ing] to reliably rule out alternative causes like Plaintiff's own skin, [OR] personnel, [and] surgical instruments" and failing to "meaningfully engage with Plaintiff's co-morbidities and medical history." ECF No. 70, at 2, 18.

Differential etiology is a method employed by physicians to form an opinion about what caused a patient's condition. *Hoefling v. U.S. Smokeless Tobacco Co., LLC*, 576 F. Supp. 3d 262, 280 (E.D. Pa. 2021). "When conducting such an analysis, the expert must rule in then rule out possible causes of the illness. . . Experts are not required to address all possible causes, but [o]bvious alternative causes need to be ruled out." *In re Zostavax (Zoster Vaccine Live) Products Liab. Litig.*, 579 F. Supp. 3d 675, 679 (E.D. Pa. 2021) (internal citations and quotations omitted). "Once a defendant points to a plausible alternative cause of the plaintiff's illness, the expert must 'offer a good explanation as to why his or her conclusion remains reliable.'" *Id*. (quoting *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 808 (3d Cir. 1997)). Although they are not required to conduct all available tests to confirm their opinions, medical experts using differential etiology need to show "good grounds" for reaching their conclusion using "sufficient diagnostic techniques." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 761 (3d Cir. 1994).

An expert may reasonably rely on "a mix of objective data and subjective analysis from another expert" in developing their own opinions as well as "various types of relevant medical information such as a physical examination, medical records, tests, medical literature, and [their own] experience.". *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, 2021 WL 662292, at *10 (E.D. Pa. Feb. 19, 2021) (internal quotations omitted); *In re Zostavax,* 579 F.Supp.3d at 679; *Phila. Trust Co. v. Temple Univ. Hosp., Inc.*, 2024 WL 5057595, at *6 (E.D. Pa. Dec. 9, 2024); *see Snider v. Sterling Airways, Inc.,* 758 F. App'x 283, 288 (3d Cir. 2018) (finding that an aircraft accident investigation expert was "permitted to rely on the findings of other experts [in the field of metallurgy] in forming his conclusions").

1. Drs. Jack Bowling and Bernard Camins

Dr. Bowling is an orthopedic surgeon with over twenty years of experience diagnosing and treating disorders of the hip and knee. Bowling Rep., ECF No. 70-3, at 1. He specializes in adult reconstructive or joint replacement surgery. *Id*. In reaching his conclusion that Plaintiff's "periprosthetic right knee joint infection was more likely than not caused by airborne contamination of the sterile field during the elective revision right knee arthroplasty surgery," Dr. Bowling relied on "[m]echanistic studies [which] confirm the Bair Hugger increases particles over the sterile field," and "peer reviewed medical literature and 3M company admissions confirming the Bair Hugger is capable of causing PJI by way of airborne contamination." [10] ECF No. 70-3, at 57.

[10] In addition to challenging the reliability of Drs. Bowling and Camins and the qualifications of Dr. Bowling, Defendants move to preclude Drs. Bowling and Camins from "mischaracterizing" statements from employees or representatives of Defendants as "admissions." ECF No. 70, at 29. The Court declines to address this matter at this time, as it is unrelated to the issue of admissibility of Drs. Bowling or Camins' specific causation opinions and can be resolved at a later time. For purposes of this opinion, where the Court must construe

Dr. Camins is a Professor of Medicine at the Icahn School of Medicine and the Medical Director of Infection Prevention at Mount Sinai Health System in New York City. Camins Rep., ECF No. 70-27, at 1. He was trained in the fields of internal medicine and infectious diseases and has extensive experience researching, teaching, and writing about healthcare epidemiology and infection prevention, especially during the perioperative period. *Id*. His conclusion that the Bair Hugger was the most likely cause of Plaintiff's PJI was based on his review of scientific literature on patient warming, infection risk, and the Bair Hugger's effect on OR airflow, Plaintiff's medical records, deposition testimony of 3M and its employees, and his own clinical training and experience. *Id*. at 11.

Defendants point to five plausible alternative causes which they allege Drs. Bowling and Camins failed to rule out: 1) OR personnel and instruments; 2) OR air; 3) bacteria already present in Plaintiff's body 4) abrasions on Plaintiff's skin and ineffective skin preparation; and 5) Plaintiff's increased infection risk from comorbidities.

The Court finds Drs. Bowling and Camins have offered sufficient explanations as to why their conclusions that the Bair Hugger was more likely than not the sole cause of Plaintiff's infection remain reliable. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 759 n.27 (3d Cir. 1994) ("thus, where a defendant points to a plausible alternative cause and the doctor offers *no* explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable."). These experts do not merely declare their opinions *ipse dixit* without citing other relevant medical information which establishes a causal connection between the Bair Hugger device and Plaintiff's infection. *See In re Zostavax,* 579 F.Supp.3d at 679. Additionally, despite Defendants' argument to the contrary, Plaintiff's experts do address the

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the facts in the light most favorable to the Plaintiff, the Court will adopt Plaintiff's characterization of these statements.

obvious alternative causes and provide sufficient explanations for why they were ruled out. Although the Court is not convinced that all five of Defendants' proposed alternative causes are obvious ones that the experts would be obligated to rule out, the Court will address them, nonetheless.

Drs. Bowling and Camins acknowledge that "inanimate objects [such as other medical devices or surgical tools] in the OR can be a potential source of contamination" and "[t]he surgical team can introduce bacteria into the sterile field and increase the risk of infection." ECF No. 70-27, at 10, 11; ECF No. 70-3, at 42-44, 51. However, Dr. Bowling rejected these inanimate objects as the cause of Plaintiff's infection where there was no definitive peer reviewed scientific literature linking the presence of these objects in the OR to "bacteria inoculating the operative site and creating a source specific surgical site infection." ECF No. 70-3, at 44. In further support of his opinion to rule out these sources as alternative causes, Dr. Bowling relied on the testimony of another expert, Dr. Godbout, regarding the sterilization procedures he used in Plaintiff's OR. *See* Bowling Dep, 70:23-71:3, ECF No. 82-21. Dr. Bowling has experience with maintaining sterility and preventing infection during the surgeries he performs, which allowed him to conclude that the similar techniques employed by Dr. Godbout during Plaintiff's procedure would have mitigated any potential risk of contamination by these objects. *See id.*, at 161:5-14; 70:23-71:3, 73:15-19; ECF No. 70-3, at 43-44. Dr. Camins reached a similar conclusion relying on his training, education, experience, and the scientific literature available to him at the time of writing his report. ECF No. 70-27, at 11. He explained that unless there was a breach in the sterile field, or these inanimate objects came in direct contact with Plaintiff's surgical site, neither of which has been reported, the mere presence of these objects in the OR could not have plausibly caused her infection. *Id*. As to OR personnel,

Dr. Bowling admits that "[p]ersonnel present in the [OR] are the main source of particles in the air" and "[d]oor openings and traffic in the OR create turbulence and contaminate ultraclean air by bacterial shedding." ECF No. 70-3, at 41. However, infection can be prevented by limiting the number of times the door opens and traffic comes in and out of the OR, which Dr. Godbout reportedly did. *Id.*; Godbout Rep., ECF No. 70-28, at 3. Therefore, Dr. Bowling ruled out OR personnel as a cause of Plaintiff's infection. Dr. Camins similarly ruled out OR personnel as a plausible alternative cause, finding that the surgical team correctly "minimized the number of surgical personnel participating in the surgery" which reduced the risk of introducing bacteria into the sterile field. ECF No. 70-27, at 10.

Second, Defendants claim Drs. Bowling and Camins improperly excluded OR air as a source of Plaintiff's infection without explanation. ECF No. 70, at 20-21. Drs. Bowling and Camins did consider and rule out OR air contamination as an alternative cause of Plaintiff's infection and sufficiently explained their reasoning. First, even though they acknowledge that the number of door openings and individuals present in the OR can increase the number of particles in the air, they report that sterile techniques were observed in Dr. Godbout's operating room to reduce that risk and prevent the introduction of bacteria into the surgical field, as discussed above. *See* ECF No. 70-3 at 25, 26, 36, 40; ECF No. 70-27, at 10. In addition, they also explain how these risks were further mitigated by the use of a unidirectional or laminar air flow ventilation system that "protects against the negative impact of room traffic and door openings on particle density" by "minimizing particulate debris in and around the surgical incision." ECF No. 70-3, at 37, 41: *see* ECF No. 70-27, at 3. Although neither doctor is an expert in airflow computation or dynamics and cannot attest to the impact of unidirectional air flow themself, they were justified in relying on their own OR experience, the findings of airflow experts, and

scientific research confirming that a laminar system was likely in place during Plaintiff's surgery. These systems have been proven to reduce the risk of bacterial contamination by "blowing air down and away from the surgical field." *See* ECF No. 70-3, at 40; ECF No. 70-27, at 3, 5, 11; 72:1-73:11, ECF No. 82-22. Drs. Bowling and Camins were justified in relying on the medical reports and testimony of Dr. Godbout who performed Plaintiff's surgery and recalled that a laminar was in place at that time and there were no reported issues with its operation. *See* Godbout Dep., 99:5-17, ECF No. 82-23; ECF No. 70-27, at 11. Therefore, in concluding that proper sterilizing techniques were used in conjunction with a laminar ventilation system to reduce the risk of airborne contamination, Drs. Bowling and Camins properly ruled out OR air as a cause of Plaintiff's PJI.

Third, Defendants allege these experts failed to consider other bacteria present in Plaintiff's bloodstream as a plausible alternative cause of her joint infection. Drs. Bowling and Camins' reports briefly discuss the potential risk of post-surgical prosthetic infections that can result from transient bacteremia triggered by infections in other parts of the patient's body, such as a urinary tract infection. ECF No. 70-3, at 26; ECF No. 70-27, at 3. However, there is very little scientific research available on this type of bacterial transmission from a remote body site, as it is "extremely rare" and occurs in only one in ten thousand cases. 19:13-19, ECF No. 82-22; ECF No. 70-22, at 3. Moreover, the Court is not convinced that this theory of intra-patient bacterial spread amounts to an obvious alternative cause, because neither Plaintiff's medical records nor her treating physician's report formally diagnosed her with a urinary tract or other infection prior to her surgery. *See* 151:7-16, ECF No. 82-21; ECF No. 70-3, at 8. At most, these sources confirmed that she had some of the symptoms consistent with a urinary tract infection. ECF No. 70-3, at 7 (reporting that Plaintiff had blood in her urine and sees a urologist routinely).

Therefore, the expert opinions will not be excluded for failure to rule out bacteria in Plaintiff's bloodstream as a cause of her PJI where there is minimal evidence to support the existence of a bacterial infection prior to surgery and minimal data supporting the plausibility of bacteria spreading from a remote body site to her knee joint.

Fourth, Defendants contest the medical experts' decision to rule out abrasions and surgical staples on Plaintiff's skin as well as ineffective skin preparation as alternative causes of her PJI. Drs. Bowling and Camins concede that an infection could plausibly result from a scrape left untreated if bacteria entered the patient's bloodstream and evaded an attack by the patient's immune system. 56:22-25, ECF No. 82-21; 119:24-120:4, ECF No. 82-22. However, finding that Dr. Godbout utilized three forms of sterilizing preparation for Plaintiff's leg prior to surgery, Drs. Bowling and Camins were satisfied to rule out ineffective skin preparation as a plausible cause of infection where one of those forms of skin preparation alone was sufficient to "nearly eliminate skin bacteria at her surgical site incision." ECF No. 70-3, at 36; 90:24-91:6, ECF No. 82-21; ECF No. 70-27, at 11; 119:24-120:13, ECF No. 82-22.; ECF No. 82-5, at 5. Despite Defendants' contentions, these conclusions were not ipse dixit. These medical experts have experience in pre-surgical skin preparation and knowledge of the benefits of certain products and procedures in preventing bacterial infections. *See* 90:20-91:11, ECF No. 82-21; 115:5-10, ECF No. 82-22. Although Defendants contest that Drs. Bowling and Camins "ignored" reported symptoms of "some bleeding from the incision after [Plaintiff's] staples [were] removed" and alleged abrasions from her fall in the pool, the Court disagrees. ECF No. 70-3, at 12. Again, there is little-to-no information contained in Plaintiff's medical records or Dr. Godbout's report concerning these injuries, and in the experts' professional experience, the sterilizing procedures used would have eliminated bacteria on the skin in any event. *See* 148:18-149:17, ECF No. 82-

21 (testifying that Plaintiff's pre-operation medical examination did not indicate signs of a soft tissue joint infection from a prior abrasion because there were no reports of visible skin changes); ECF No. 70-3, at 55 (noting the absence of any documented abrasions or signs of skin infection present prior to Plaintiff's surgery); 153:14-25, ECF No. 82-21 (explaining that the presence of blood was not uncommon when removing surgical staples, and "of itself does not indicate a hematoma. . . abscess . . . or infection"). Therefore, the Court finds the experts have provided sufficient explanations for why their conclusions remain reliable and why these alternative causes were not plausible.

Finally, Defendants argue that both experts "fail[] to meaningfully address the increased infections risks posed by Plaintiff's comorbidities, including how they might affect her risk of infection from alternative sources like her own body." ECF No. 70, at 23. However, although these comorbidities can increase the risk of Plaintiff's infection, they do not independently cause infection, as that requires the introduction of bacteria into the surgical site. ECF No. 70-3, at 29; ECF No. 70-27, at 3. At this stage, the Court is tasked only with assessing whether the medical experts effectively ruled out obvious alternative causes. Therefore, it is not necessary to discuss whether these experts meaningfully addressed and explained why they ruled out Plaintiff's comorbidities in their reports, as these comorbidities could not have plausibly caused her contamination. For the reasons discussed above, the Court concludes that Drs. Bowling and Camins' testimonies are reliable.

Defendants raise an additional argument as to Dr. Bowling's qualification as an expert. They contest that because Dr. Bowling has experience only as an orthopedic surgeon and not an epidemiologist or infectious disease specialist, he is unqualified to give the following opinions:

- Plaintiff's periprosthetic right knee joint infection was more likely than not

caused by airborne contamination of the sterile field during the elective revision right knee arthroplasty surgery, August 22, 2018. (Ex. A, Bowling Rep. 57.)

- Mechanistic studies confirm the Bair Hugger increases particles over the sterile field. (*Id.*)
- Airborne contamination caused by use of the Bair Hugger during Plaintiff's surgery was the most probable cause of her bacterial PJI.

ECF No. 70, at 28. We disagree. "As long as an expert possesses relevant qualifications as to a topic or area of knowledge, the fact that they do not have special skills in the most relevant subspeciality does not render them unqualified to testify." *Philadelphia Trust Co.*, 2024 WL 5057595, at *3 (quoting *Power*, 2023 WL 2705237, at *6); *see Pineda,* 520 F.3d at 245 (finding an expert was qualified "even though he may not have been the 'best qualified' expert or did not have the 'specialization' that the District Court deemed necessary."). In a recent case in this district, a neonatologist and pediatric neurologist were permitted to testify as to the causation of a newborn child's hypoxic brain injury even though they were neither obstetricians nor experts in maternal fetal medicine because their background and everyday experience involved the diagnosis and treatment of those types of injuries. *Philadelphia Trust Co.*, 2024 WL 5057595, at *3. The same goes here. Defendants' argument against the admissibility of Dr. Bowling's qualification to give the proffered opinions is supported only by the fact that he has admitted in deposition testimony for another case that he is neither an infectious disease specialist nor an expert in operating room or HVAC system design. ECF No. 70, at 28; Bowling Dep., 56:14-25, ECF No. 70-25. However, that is not what the standard in this Circuit requires. Dr. Bowling does not need to be the best qualified expert or possess the most relevant special skills for his opinion

to be admissible. Although Dr. Bowling is not a self-proclaimed expert in epidemiology or infectious diseases, his work in orthopedic surgery requires him to understand the potential complications of each surgery he performs, and "[i]nfection is the leading cause of failure after total joint arthroplasty." ECF No. 70-3, at 37. Therefore, he possesses relevant qualifications and knowledge regarding the causes of post-operative infection and methods to prevent it, including the use of surgical devices that will not interrupt the unidirectional air ventilation systems. *Id*. at 37-38. The fact that Dr. Bowling is not an epidemiologist or infectious disease specialty goes to the weight of his testimony and not the admissibility. *Cree v. Hatcher*, 969 F.2d 34, 38 n.5 (3d Cir. 1992). Moreover, we concur with the finding in *Philadelphia Trust. Co.*, that the fact that Dr. Bowling "rel[ies] in part, on other experts' interpretations of certain evidence in coming to [his] separate causation opinion[s] is of no moment," so long as it is not the sole foundation for his opinion. 2024 WL 5057595, at 4. The Court concludes he is qualified to offer the opinions listed above.

2. Dr. Brett Godbout

Dr. Godbout, the orthopedic surgeon who performed Plaintiff's total knee arthroplasty, maintains that airborne contamination was the most likely cause of Plaintiff's PJI. ECF No. 70-28, at 3. Dr. Godbout admits that infection is a likely risk of any surgery, and "the vast majority of PJIs result from contamination during surgery." *Id*.; 221:17-222:9, ECF No. 70-29. Therefore, Dr. Godbout took measures to prevent contamination, including cleaning the surgical site three times, wearing two pairs of gloves during surgery, changing his gloves before making the incision and touching the implant, irrigating the incision with antibiotics, and limiting the number of personnel in the OR. ECF No. 70-28, at 3.

Defendants challenge Dr. Godbout's reliability for failure to rule out alternative causes including the omnipresent risk of infection in every surgical procedure. ECF No. 70, at 27. Defendants argue that because Dr. Godbout is aware that every surgical procedure presents a risk of infection, he was required to rule out alternative causes of this infection before concluding that the Bair Hugger was the most likely cause. *See* ECF No. 70, at 27. The Court finds he has sufficiently explained why he ruled out these sources because the preventative measures he took and sterilization techniques he used, in his experience, would have decreased the plausibility that they could cause airborne contamination. *See* 159:13-24, ECF No. 70-29; ECF No. 70-28, at 3. Defendants also argue that Dr. Godbout's testimony is unreliable because he did not investigate the cause of the bacterial infection when Plaintiff first came to him, he focused only on treating it. *Id*. Although some may argue this was not the best practice, the Court does not find it dispositive to the determination of whether the methodology Dr. Godbout used in determining the cause of Plaintiff's infection after it was treated was reliable. *Andrews v. Brethren Mut. Ins. Co.*, 2023 WL 6690710, at *6 (M.D. Pa. Oct. 12, 2023) ("Reliability does not require that the opinion is supported by the best methodology or unassailable research." (internal quotations omitted)).

IV. SUMMARY JUDGMENT

Federal Rule of Civil Procedure 56(a) sets forth the standard for reviewing a motion for summary judgment. Summary judgment is appropriate "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Once the moving party has met its initial burden, the nonmoving party must set forth specific facts—through citation to affidavits, depositions, discovery documents, or other

evidence—that demonstrate the existence of a genuine triable dispute. *Maietta v. C.R. Bard, Inc.*, 2022 WL 3577374, at *2 (E.D. Pa. Aug. 19, 2022) (citing Fed. R. Civ. P. 56(c)).

If there is "no genuine issue as to any material fact," the moving party is entitled to judgment as a matter of law. *Id*. at 323. A genuine dispute exists where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party" and a material fact is one that "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986). In reviewing the facts before it, the Court must draw them in the light most favorable to the non-moving party. *Doe v. Centre County*, 2 42 F.3d 437, 446 (3d Cir. 2001).

A. Statute of Limitations [11]

Defendants seek to dismiss Plaintiff's negligence, failure to warn, and design defect claims under Pennsylvania's two-year statute of limitations for tort claims. *See* 42 Pa. C.S. § 5524(2). Defendants argue that the statute of limitations began to run on the date of Plaintiff's surgery when the injury from the use of the Bair Hugger was inflicted, on August 22, 2018. ECF No. 71, at 9. Therefore, Plaintiff had until August of 2022 to file her complaint, and her filing on August 4, 2023, was untimely. *Id*. Plaintiff in response argues that the discovery rule is applicable to toll the commencement of the statute of limitations until September 7, 2021, at the earliest. ECF No. 85, at 7.

In Pennsylvania, the discovery rule, when applicable, tolls the statute of limitations "until a plaintiff could reasonably discover the cause of his action, including in circumstances where

[11] Defendants do not challenge Plaintiff's design defect claim on any additional grounds outside of its untimeliness. The Court will not address the merits of this claim at this time where Defendant has not argued against them. *See Smith v. McKinney*, Case No. 2:22-cv-02983-JDW, 2023 WL 3543531, at *10 (E.D. Pa. Oct. 6, 2023) ("Because Defendant's don't argue about the other elements of the claim, I do not have to address them.").

the connection between the injury and the conduct of another are not readily apparent." *Presbury v. Correct Care Solution Inc.*, 2022 WL 1787333, at *7 (E.D. Pa. May 31, 2022) (quoting *In re Risperdal Litig.*, 223 A.3d 633, 640 (Pa. 2019)). "The purpose of this rule is clear: to 'ensure that persons who are reasonably unaware of an injury that is not immediately ascertainable have essentially the same rights as those who suffer an immediately ascertainable injury.'" *Rice v. Diocese of Altoona-Johnstown*, 255 A.3d 237, 247 (Pa. 2021) (quoting *Nicolaou v. Martin*, 195 A.3d 880, 892 n.13 (2018)). Under the inquiry notice approach adopted in Pennsylvania, the statute of limitations begins to run when the plaintiff knew or, exercising reasonable diligence, should have known (1) he or she was injured and (2) that the injury was caused by another." *Adams v. Zimmer US, Inc.*, 943 F.3d 159, 163 (3d Cir. 2019). When analyzing the discovery rule at the summary judgment stage, a court must "consider whether it is undeniably clear that [Plaintiff] did not use reasonable diligence in timely ascertaining [her] injury and its cause [on her own], or whether an issue of genuine fact exists regarding [her] use of reasonable diligence to ascertain [her] injury and its cause." *Adams v. Zimmer US, Inc.*, 943 F.3d 159, 164 (3d Cir. 2019) (quoting *Gleason v. Borough of Moosic*, 15 A.3d 479, 484 (Pa. 2011)).

Although the applicability of the discovery rule can be decided on summary judgment, the Supreme Court of Pennsylvania has held that in certain instances, "[g]iven the lengthy history of attempted contradictory diagnosis and treatment, the date of accrual [for inquiry notice purposes] could not be determined as a matter of law by the court[,] and a jury would decide when [plaintiff] knew of an injury redressable by a lawsuit." *DiDomizio v. Jefferson Pulmonary Associates*, 280 A.3d 1039, 1049 (Pa. Super. 2022) (quoting *Nicolaou*, 649 Pa. at 894)); *see Presbury*, 2022 WL 1787333, at *7. Although Plaintiff was aware that she had an infection, she was never given any inclination from her doctors as to what the cause of that infection was. *See*

ECF No. 85, at 8. Neither the orthopedic surgeon who performed her surgery, nor the infectious disease specialists at the inpatient facility were able to provide an explanation. RSUMF, at P ¶¶ 9, 12. Pennsylvania case law does not expect a Plaintiff to have "more medical knowledge than their doctors or health care providers have communicated to them." *Adams*, 943 F.3d at 163. Therefore, it would be inappropriate to charge Plaintiff with constructive knowledge of the cause of her infection where her health care providers lacked such knowledge.

The Court also finds there is a genuine dispute of fact over whether Plaintiff was put on inquiry notice by a cold call that she received prior to initiating the current lawsuit. On one hand, Defendants have put forth evidence that Plaintiff received a cold call from a woman with a Southern accent inquiring about her recent post-surgical infection "at least six months" before she retained the law firm of McDonald Worley to represent her on September 7, 2021. *See* SUMF, at ¶¶ 26, 28, 29. Therefore, Defendants proffer that the cold call occurred sometime in March of 2021 and was sufficient to put Plaintiff on notice of the cause of her injury because she has admitted it is what prompted her to file the current lawsuit. ECF No. 71, at 11; s*ee* RSUMF, at R ¶ 31. On the other hand, Plaintiff provides rebuttal evidence that the cold call occurred six months prior to a second phone call with a paralegal at McDonald Worley, not six months prior to her retaining the law firm. *See* ECF No. 85, at 13; RSUMF, at P ¶ 22. This phone call with the paralegal allegedly took place six months after she retained the law firm on September 7, 2021. *See* ECF No. 85, at 13. Therefore, Plaintiff argues that drawing all inferences in her favor, the Court must conclude that the cold call occurred no later than September 7, 2021. Plaintiff further argues that regardless of when the cold call occurred, it was insufficient to put her on inquiry notice of the cause of her injury, as the cold caller never identified herself or discussed the Bair

Hugger, and Plaintiff was not aware of its use in her surgery until September 9, 2021. *See id*., at 14; RSUMF, at P ¶¶ 18, 19, 23.

It is not undeniably clear to the Court that Plaintiff did not use reasonable diligence in timely ascertaining the cause of her injury. Plaintiff is not expected to know more about her injury than her treating physicians, who never informed her prior to this suit that the Bair Hugger might have caused her injuries. There is a genuine issue of fact as to when the cold call occurred and whether it was sufficient to notify Plaintiff of the causal connection between the use of the Bair Hugger in her surgery and her PJI. Therefore, the Court finds that the issue of whether the discovery rule applies to toll the statute of limitations is best left for the jury to decide. *See Gleason v. Borough of Moosic*, 15 A.3d 479, 485 (Pa. 2011).

B. General and Specific Causation

For the reasons discussed at length above, and in consideration of the Court's decision to admit Plaintiff's proposed general and specific causation experts, the Court finds there is sufficient evidence of the required element of causation for a reasonable juror to find in Plaintiff's favor on her tort claims. *See Keen v. C.R. Bard, Inc.,* 480 F.Supp.3d 624, 637 (E.D. Pa., 2020) (showing that causation is a required element of negligence, failure to warn, and design defect claims); *Ream*, 2020 WL 6889238, at *4 (finding that in Pennsylvania "a plaintiff must establish [both general and specific] causation through admissible expert testimony"). The result reached by the Eighth Circuit regarding the admissibility of these general causation opinions still stands under Third Circuit precedent following the 2023 amendment to Rule 702. The evidence proffered by Plaintiff's general and specific causation experts establishes a prima facie showing of causation.

C. Failure to Warn

Defendants raise two additional challenges to Plaintiff's failure to warn claim: 1) that they owed no duty to warn and 2) that any failure to warn would not have prevented Plaintiff's doctors from using the Bair Hugger in her surgery. ECF No. 71, at 21, 23.

"In order to state a claim for negligent failure to warn under Pennsylvania law, a plaintiff must show that (1) the defendant manufacturer owed a duty to the plaintiff; (2) the manufacturer breached that duty; and (3) that breach was the proximate cause of the plaintiff's injuries." *Cohen v. Johnson & Johnson,* 634 F. Supp. 3d 216, 237 (W.D. Pa. 2022). In an action against the manufacturer of a medical device, "the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate." *Keen,* 480 F.Supp.3d at 641 (quoting *Daniel v. Wyeth Pharms., Inc.*, 15 A.3d 909, 924 (Pa. Super. Ct. 2011)). The adequacy of a warning is most often established through expert testimony. *Soufflas v. Zimmer, Inc.*, 474 F.Supp.2d 737, 751 (E.D. Pa., 2007). An adequate warning both "(1) accurately and unambiguously convey[s] the scope and nature of the risk, and (2) state[s] the risk with sufficient specificity." *Keen,* 480 F. Supp. 3d at 641 (quoting *Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448, 462 (W.D. Pa. 2019)). However, if the Court finds the manufacturer did not owe a duty to warn under the first requirement, the claim fails altogether. A duty to warn is owed in the case of dangers that are known or should reasonably be known. *See McPeak v. Direct Outdoor Products, LLC*, 2022 WL 4369966, at *3 (E.D. Pa. Sep. 20, 2022) (citing Restatement (Second) Torts § 388).

Defendants argue they had no duty to warn because there were no risks known to them from the scientific and medical data available at the time of Plaintiff's surgery. ECF No. 71, at 21. In support of this, Defendants point to a Safety Alert issued by the FDA which informed health care providers that "forced air warming thermoregulation systems [have] been

demonstrated to result in . . . decreased risk of infection for patients." RSUMF, at R ¶ 21. However, Plaintiff has put forth various types of rebuttal evidence in support of her argument that Defendants knew, or at the very least should have known of the risk of PJIs from the use of the Bair Hugger. First, as discussed above, some of the scientific studies Plaintiff's medical experts relied on in reaching their general causation opinions were published prior to Plaintiff's surgery and identified an association between the use of the Bair Hugger and an increased risk of airborne contamination. *See, e.g.*, McGovern 2011, Ex. O, ECF No. 70-17, at 1541. Second, Plaintiff has provided numerous statements from Defendants' Clinical Research Director that confirm his awareness of the risk of infection as well as the awareness of others in his department when he began working for Defendants in 1994. *See* RSUMF, at P ¶¶ 28, 30; RSUMF, at R ¶ 14. Lastly, Plaintiff has provided evidence from a label Defendants included on the original Bair Hugger model and filings made with the FDA which both warned of the possibility of airborne contamination. RSUMF, at P ¶ ¶ 24, 29. Construing the facts in the light most favorable to Plaintiff, the Court finds a reasonable jury could conclude Defendants had knowledge of the risk of PJIs from use of the Bair Hugger.

As a part of the proximate causation analysis, Pennsylvania requires plaintiffs to show that "a different warning "could have made a difference to the specific prescribing [or treating] physician in the specific case." *Cohen,* 634 F. Supp. 3d at 237. Plaintiff has provided statements directly from Dr. Godbout who claimed he would not have allowed the Bair Hugger to be used in Plaintiff's surgery if he had been made aware "that use of the Bair Hugger increases particles over the surgical site," "the machine harbors bacteria," the device was "contraindicated in orthopedic implant surgeries," or the device increases the risk of PJIs. *See* Godbout Dep. 140:2-11, ECF No. 83-1; RSUMF, at P ¶ ¶ 31-32. Defendants alternatively allege that the relevant

physician for purposes of this proximate causation analysis is not the orthopedic surgeon, but the anesthesiologist who had the authority to decide what patient warming device would be used in the ORs of Coordinated Health. *See* Zarrelli Dep., 125: 1-11, ECF No. 71-3. Dr. Stephen Zarrelli testified that he continues to use the Bair Hugger in surgical procedures and to the best of his knowledge, it is a safe and effective method for patient warming. *Id.*, 208:15-209:13. However, Plaintiff argues that a warning would have also made a difference in Dr. Zarrelli's decision to use the Bair Hugger in her OR, because he admitted that he was not informed by the manufacturer of any complications from using the device, such as if it was contraindicated in orthopedic surgeries. *Id*. 151:6-153:20. The Court finds Plaintiff has here too demonstrated a dispute of fact over whether a different warning would have made a difference to the treating physicians in her case and prevented them from using the Bair Hugger in her operating room.

D. Fraud

Plaintiff's fraud claim is premised on two theories, fraudulent misrepresentation and fraudulent concealment. Plaintiff alleges Defendants misrepresented the safety of the Bair Hugger for use in surgical procedures by disclosing false information or failing to disclose material information to her physicians. ECF No. 63, at ¶¶ 182-83.

"Under Pennsylvania law, to establish a common law intentional misrepresentation claim a plaintiff must show that there was '(1) a representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and, (6) the resulting injury was proximately caused by the reliance.'" *Cohen,* 634 F.Supp.3d at 234 (quoting *Bortz v. Noon*, 556 Pa. 489, 499 (1999)). "[T]he elements of fraudulent concealment are identical [to fraudulent misrepresentation] except that the wrongdoer

intentionally conceals a material fact rather than making an affirmative misrepresentation." *Maietta,* 2022 WL 3577374, at *7 (quoting *Manning v. Temple Univ.,* 2004 WL 3019230, at *10 (E.D. Pa. Dec. 30, 2004)). In products liability actions, a plaintiff must show that material information was misrepresented or concealed from her implanting physician. *See Cohen*, 634 F. Supp. 3d at 234.

In their motion, Defendants dispute the misrepresentation and reliance elements of Plaintiff's claim of fraud, alleging that all of their representations about the Bair Hugger's safety have reigned true, and any omissions or false statements did not induce reliance because Plaintiff's anesthesiologist still considers the Bair Hugger safe and uses it presently. *See* ECF No. 71, at 26. Plaintiff has first alleged facts that Defendants knew of the Bair Hugger's capability to cause PJIs when used in orthopedic surgeries yet misrepresented its safety and omitted this information when communicating to both Drs. Godbout and Zarrelli. *See* ECF No. 85, at 23-24. These physicians testified that they relied on Defendants "to provide accurate information about the dangers posed by the Bair Hugger." ECF No. 85, at 23-24. A jury may credit this testimony and agree with Plaintiff that Drs. Godbout and Zarrelli relied on Defendants to "disclose more accurate, detailed information than what was actually communicated to [them]" about scientific studies connecting the Bair Hugger to an increased risk of airborne contamination and development of PJIs. *Maietta,* 2022 WL 3577374, at *7. Plaintiff has adequately demonstrated genuine disputes of fact as to the misrepresentation and reliance elements of her fraud claim.

E. Punitive Damages

Finally, Plaintiff argues that punitive damages are warranted because of Defendants' conduct both in its representations to Plaintiff's physicians about the safety of the Bair Hugger

and in "fail[ing] to conduct studies to adequately review the relationship between the Bair Hugger and PJIS" was "outrageous." ECF No. 85, at 24-25.

In Pennsylvania, punitive damages are an extreme remedy awarded where a defendant has "acted in an outrageous fashion due to either the defendant's evil motive or his reckless indifference to the rights of others." *Keen,* 480 F. Supp. 3d at 646 (*quoting Phillips v. Cricket Lighters*, 883 A.2d 439, 445 (Pa. 2005). However, "[b]ecause the determination of whether a defendant's conduct rises to the level of outrageousness is a role for the finder of fact," my colleagues in this District determined "the Court should decide the viability of a punitive damages claim, 'only when no reasonable inference from the facts alleged supports a punitive award.'" *Id*. (quoting *Soufflas*, 474 F. Supp. 2d at 756). Again, viewing the facts in the light most favorable to Plaintiff, the Court finds that a reasonable inference could be drawn which would support a punitive award.

V. CONCLUSION

Plaintiff has proven by a preponderance of the evidence that her general and specific causation experts satisfy the three admissibility requirements of Rule 702: qualification, reliability, and fit. The Court, therefore, denies Defendants' motion to exclude (ECF No. 70). Drawing all factual inferences in Plaintiff's favor, the Court also finds that there are genuine disputes of fact regarding the discovery rule and her claims of negligence, design defect, failure to warn, and fraud, and whether punitive damages are appropriate. Defendants' motion for summary judgment (ECF No. 71) is also denied. An appropriate order follows.

BY THE COURT:

/s/ John M. Gallagher
JOHN M. GALLAGHER
United States District Court Judge